

REMARKS

Upon entry of this paper, claims 1 and 11 have been amended, claims 6 and 16 have been canceled, and no claims have been added as new claims. Thus, claims 1, 2, 4-15 and 17-20 are currently pending in the application, of which claims 1 and 11 are independent.

Claims 1 and 11 have been amended to clarify that plurality of branches bend radially outwardly and simultaneously are compressible to a first screw diameter without plastic deformation. This amendment is supported throughout the specification, including on page 4, lines 19-26, on page 6, lines 1-12 and lines 14-20, and in Figs. 3, 4 and 5. Claims 1 and 11 have also been amended to incorporate dependent claims 6 and 16 which clarify that the screw head is disposed at a different end of the bone screw than the end from which the slots are formed. Support for this amendment appears throughout the specification, including Fig. 1. No new matter has been added.

Interview Summary

Applicant thanks the Examiner for attempting to clarify the record regarding the interview summary. Applicant confirms the description of what occurred during the telephone interview as described in Applicant's reply of June 29, 2006.

Claimed Invention

The claimed invention is generally directed to a furcated orthopedic bone screw including a threaded portion that is cut or slotted into multiple radial segments. Each of the radial segments of the furcated bone screw bends in a radially outward direction to create a compressible screw tip of increasing diameter over the furcated portion of the screw. In use, the radial force of the threaded radial segments against the bone or prosthetic results in the furcated bone screw being better able to engage the bone or prosthetic to resist pull-out and compensate for stripped threads or soft bone.

Claim Rejections – 35 USC § 102

Claims 1-7 and 9-20 were rejected under 35 USC 102(e) as being anticipated by International PCT Application WO 02/34120 of Dudasik. Applicant amends claims 1 and 11, and in addition provides the following remarks in support of patentability of the pending claims.

The Dudasik reference is generally directed to devices used in surgery for joining together bone and/or tissue. The devices typically are inserted into a hole created in the bone or tissue. Dudasik discloses a combination of an expansion sleeve and an inner expander used as a fixation device.

The Dudasik reference does not disclose each and every element of the claimed invention. Specifically, the Dudasik reference does not disclose, “*wherein the plurality of branches bend radially outwardly from a first screw diameter to a relatively larger second circumferential diameter and simultaneously are compressible to the first screw diameter without plastic deformation,*” as recited in amended independent claim 1. The Office Action cites Figs. 7A-7C and page 6, 2nd paragraph, to support the contention that the Dudasik reference discloses the aforementioned elements of claim 1. Fig. 7A shows an expansion sleeve 12 and an expander 34. There is no indication whatsoever that the sections of the expansion sleeve are bending, or are bent, radially outwardly in Fig. 7A. In Fig. 7C, the expander 34 has been forced into the expansion sleeve 12 which results in the sections expanding outward. However, when the sections are expanded outward, the sections are not simultaneously compressible to the first diameter because the expander inside the sleeve physically prevents the sections from compressing to the first diameter, with or without plastic deformation. Either the sections of the expansion sleeve do not bend radially outward, but may be compressed, as in Fig. 7A, or the expander has been inserted so that the sections expand radially outward, but they cannot be compressed to the first diameter as in Fig. 7C. Due to the fundamental differences in design between the invention of claim 1 and the invention disclosed in the Dudasik reference, the invention disclosed in the Dudasik reference does not permit branches that *bend radially outwardly from a first screw diameter to a relatively larger second circumferential diameter and simultaneously are compressible to the first screw diameter without plastic deformation*, as recited in amended independent claim 1.

The Office Action states that Dudasik discloses, “the plurality of furcated branches can compress to the first screw diameter state when the fastener is initially positioned at the opening of a hole,” and “the plurality of furcated branches return to the second circumferential diameter upon reduction of a radially compressive force.” As can be seen in Fig. 7A of Dudasik, when

the fastener is initially positioned at the opening of a hole the sleeve is not expanded and so the sleeve is already in the first diameter state. The sections of the slotted sleeve do not “compress” to the first diameter state because they are already in the first diameter state. The sections of the slotted sleeve do not “return” to the second circumferential diameter upon “reduction of a radially compressive force” because they cannot “return” to a diameter that they never previously had. Instead, the sections of the slotted sleeve in Fig. 7C of the Dudasik reference go from a first diameter to a second larger circumferential diameter only when the expander is inserted in to the sleeve.

The Dudasik reference does not disclose each and every element of amended independent claim 1. Thus, Applicant respectfully submits that amended independent claim 1 is in condition for allowance. Accordingly, withdrawal and reconsideration of the rejection of claim 1 is requested.

Additionally, Applicant respectfully submits that the Dudasik reference does not disclose each and every element of amended independent claim 11. Specifically, the Dudasik reference does not disclose, “*wherein the furcated means extend radially outwardly and simultaneously are compressible,*” as recited in claim 11. As was discussed in the previous section, Fig. 7C shows a sleeve and expander combination with sections expanded outwardly, but the sleeve sections are not compressible when the expander section is inserted because the expander physically blocks compression of the sleeve sections. The Dudasik reference discloses an expansion sleeve with sections that may be compressible, as in Fig. 7A, or that extend radially outward, as in Fig. 7C, but not both simultaneously. Thus, the Dudasik reference does not disclose each and every element of amended independent claim 11, which is therefore allowable. Applicant respectfully requests reconsideration and withdrawal of the rejection of amended independent claim 11.

Claims 2, 4-7 and 9-10 depend from amended independent claim 1, and are therefore allowable as depending from an allowable base claim, in addition to reciting their own patentable subject matter. Claims 12-15 and 17-20 depend from amended independent claim 11, and are therefore allowable as depending from an allowable base claim, in addition to reciting

their own patentable subject matter. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 2-7, 9-10 and 12-20.

Claims 1-7 and 9-20 were rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,436,099 to Drewry et al. Applicant has amended claims 1 and 11 to clarify the relative positions of the screw head, the screw thread, and the furcated branches, and provides additional remarks below.

The Drewry reference is generally directed to an adjustable length tether for use in the spine and other parts of the body. The tether comprises an artificial strand with an eyelet formed in one end, the other end being looped through the eyelet. The other end is then secured with respect to the eyelet by a crimp.

The Drewry reference does not disclose each and every element of the claimed invention. Specifically, the Drewry reference does not disclose *“a screw head disposed at the first end; a screw thread extending from the second end and circumnavigating the shaft; and a plurality of elongate slots longitudinally formed in the shaft from the second end and creating a plurality of furcated branches,”* as recited in amended independent claim 1. The Office Action cites Fig. 9E to support the assertion that Drewry discloses the claimed invention. As can be seen in Fig. 9E, the end of the crimp in which the slots are formed is the same end where the screw head is disposed. In contrast, claim 1 recites a *“screw head disposed at the first end”, “a screw thread extending from the second end”,* and *“elongate slots longitudinally formed from the second end of the shaft.”* The Drewry reference discloses slots and a screw head at the same end of a crimp, while the claimed invention recites slots and a screw head formed in different ends of the bone screw. The present invention is a bone screw better able to resist pull-out. As the bone screw progresses past the initial hole and through the bone the branches expand. The expansion results in a screw shaft in the bone with a larger circumferential diameter than the initial entry hole, which better resists pull-out from the bone and can compensate for stripped threads, (page 6, line 14 to page 7, line 5 and Fig. 5). The Drewry reference discloses a crimp whose branches are used to grip an artificial strand. Because the sections of the crimp are formed in the same end as the head of the crimp, the initial entry hole of the crimp is larger than the diameter of a portion of the crimp that extends further into the bone. This results in a crimp whose branches can grip

an artificial strand, but a crimp that is less able to resist pullout and cannot compensate for stripped threads. Drewry does not disclose each and every element of amended independent claim 1, which is therefore allowable. Reconsideration and withdrawal of the rejection of claim 1 is respectfully requested.

Additionally, the Drewry reference does not disclose each and every element of amended independent claim 11. Specifically, the Drewry reference does not disclose “*a screw head disposed at the first end; a screw thread extending from the second end and circumnavigating the shaft; and a plurality of elongate slots longitudinally formed in the shaft from the second end and creating a furcated means,*” as recited in amended independent claim 11. As was discussed in the previous paragraph, the Drewry reference discloses a mechanical crimp whose “head” is at the same end of the crimp as the end in which a slot is formed. In claim 11, the screw head is disposed at a different end of the screw from the end in which the longitudinal slots are formed. The Drewry reference does not teach each and every element of amended independent claim 11, which is therefore allowable. Reconsideration and withdrawal of the rejection of claim 11 is respectfully requested.

As was discussed previously, claims 2, 4-7 and 9-10 depend from amended independent claim 1, and are therefore allowable as depending from an allowable base claim, in addition to reciting their own patentable subject matter. Claims 12-15 and 17-20 depend from amended independent claim 11, and are therefore allowable as depending from an allowable base claim, in addition to reciting their own patentable subject matter. Thus, Applicant again respectfully requests reconsideration and withdrawal of the rejection of claims 2, 4-7, 9-10, 12-15 and 17-20.

Claim Rejections – 35 USC § 103

Claim 8 was rejected under 35 USC 103(a) as being unpatentable over Dudasik. Applicant amends claim 1, from which claim 8 depends, and in addition provides the following remarks in support of patentability of the pending claim.

The Dudasik reference does not teach or suggest each and every element of claim 8. The Office Action states that “Dudask discloses the claimed invention except for the plurality of furcated branches comprises three branches.” Applicant submits that the previous remarks

establish that the Dudasik reference does not disclose each and every element of amended independent claim 1, from which claim 8 depends. Applicant further submits that the Dudasik reference does not teach or suggest “*wherein the plurality of branches bend radially outwardly from a first screw diameter to a relatively larger second circumferential diameter and simultaneously are compressible to the first screw diameter without plastic deformation,*” as recited in amended independent claim 1. The Dudasik reference does not teach or suggest each and every element of claim 1 or its dependent claim 8, thus claim 8 is allowable. Further, the subject matter of claim 8 is not obvious in light of the Dudasik reference. Reconsideration and withdrawal of the rejection of claim 8 is respectfully requested.

Claim 8 was rejected under 35 USC 103(a) as being unpatentable over Drewry et al. Applicant amends claim 1, from which claim 8 depends, and in addition provides the following remarks in support of patentability of the pending claim.

The Drewry reference does not teach or suggest each and every element of claim 8. Applicant submits that the remarks above establish that the Drewry reference does not disclose each and every element of amended independent claim 1, from which claim 8 depends. Applicant further submits that the Drewry reference does not teach or suggest, “*a screw head disposed at the first end; a screw thread extending from the second end and circumnavigating the shaft; and a plurality of elongate slots longitudinally formed in the shaft from the second end and creating a plurality of furcated branches,*” as recited in amended independent claim 1, from which claim 8 depends.

Applicant further submits that the Drewry reference only discloses two branches for the crimp. There is no evidence that the optimum number of branches for a crimp, which is designed to hold an artificial fiber through compression radially inward, would be the same as the optimum number of branches in certain implantation scenarios for a bone screw designed to exert force radially outward against a bone. The choice of three branches is not obvious in light of the Drewry reference.

The Drewry reference does not disclose, teach or suggest all of the elements of claim 8. Further, claim 8 is not obvious in light of the Drewry reference, thus claim 8 is allowable.

Accordingly, Applicant again respectfully requests reconsideration and withdrawal of the rejection of claim 8.

CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicant courteously solicits allowance of the claims in the form of a Notice of Allowance. Each of the Applicant's claims contains characteristics that are neither disclosed nor suggested by the cited documents. For the reasons detailed herein, Applicant respectfully requests that all rejections be reconsidered and withdrawn. This application is in condition for allowance, and notice of the same is earnestly solicited. Should the examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact Applicant's representative by telephone at the number indicated below.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely.

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Respectfully submitted,

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